

REMARKS

Applicant respectfully requests reconsideration. Claims 1, 4-8, 10, 11, 13, 14, 17-21, 23, 24, 27-30 and 32 were previously pending in this application. Claims 1, 14 and 24 have been amended. Support for the amendments is found throughout the specification and at least on page 1, paragraphs 5 and 6, page 2, paragraph 13 and page 4, paragraph 33. New claims 33 and 34 have been added. Support for these claims is found throughout the specification and at least on page 2, paragraphs 11 and 13. As a result, claims 1, 4-8, 10, 11, 13, 14, 17-21, 23, 24, 27-30, 32, 33 and 34 are pending for examination with claims 1, 14 and 24 being independent claims and claims 10, 13, 23 and 32 being withdrawn. No new matter has been added.

Generic and Species Claims

The present application was previously the subject of a species election. Applicant has amended claim 24 to address a rejection under 35 U.S.C. § 112, as discussed in more detail below. As a result, amended claim 24 is generic to cancer and goes beyond the species election of colorectal cancer. Applicant has also added new claims 33 and 34 which depend from claim 24. Claim 34 recites cancers that go beyond the species election of colorectal cancer. However, it is understood that the claims will be examined based on the species election of colorectal cancer.

Applicant requests that upon allowance of generic claims, the claims drawn to nonelected species which require all the limitations of the generic claims be found allowable and rejoined according to MPEP § 806.04(d) and § 821.04.

Provisional Double Patenting Rejection

The Examiner rejected claims 1, 4-8, 11, 14, 17-21, 24, and 27-30 as being unpatentable over claims 6-7 of copending Application No 11/090479 in view of Ahlquist *et al.* and Hromadnikova *et al.*

Applicant respectfully disagrees. However, without acquiescing to the Examiner's position and in the interest of furthering prosecution, Applicant has amended the claims to recite that the quantitative amount of genome equivalents is measured by measuring an amount of fragments of

less than 200 bp. Support for this amendment is found throughout the specification and at least on page 4, paragraph 33. The above-cited US patent and references do not teach measuring an amount of fragments less than 200 bp to determine a quantitative amount of genome equivalents that is used to evaluate whether a patient is a candidate for additional testing for the presence of cancer.

Accordingly, withdrawal of the rejection of claims 1, 4-8, 11, 14, 17-21, 24, and 27-30 is respectfully requested.

Nonstatutory Obvious Double Patenting Rejection

The Examiner rejected claims 1, 4-8, 11, 14, 17-21, 24, and 27-30 as being unpatentable over (a) claims 1-4 of U.S. Patent No. 6,919,174, in view of Ahlquist *et al.* and Hromadnikova *et al.*; (b) claims 1-4 of U.S. Patent No. 6,964,846, in view of Ahlquist *et al.* and Hromadnikova *et al.*; (c) claims 1-4 of U.S. Patent No. 6,143,529, in view of Ahlquist *et al.* and Hromadnikova *et al.*; and (d) claims 1-4 of U.S. Patent No. 6,268,136, in view of Ahlquist *et al.* and Hromadnikova *et al.*

Applicant respectfully disagrees. However, without acquiescing to the Examiner's position and in the interest of furthering prosecution, Applicant has amended the claims to recite that the quantitative amount of genome equivalents is measured by measuring an amount of fragments of less than 200 bp. Support for this amendment is found throughout the specification and at least on page 4, paragraph 33. The above-cited US patents and references do not teach measuring an amount of fragments less than 200 bp to determine a quantitative amount of genome equivalents that is used to evaluate whether a patient is a candidate for additional testing for the presence of cancer.

Accordingly, withdrawal of the rejection of claims 1, 4-8, 11, 14, 17-21, 24, and 27-30 is respectfully requested.

Rejections under 35 U.S.C. §112

The Examiner rejected claims 24 and 27-30 under 35 U.S.C. §112, first paragraph, for failing to comply with the enablement requirement for diagnosing the health of a patient.

Applicant respectfully disagrees, but without acquiescing to the Examiner's position and in the interest of furthering prosecution, has amended claim 24 to recite a method for diagnosing

cancer in a patient. Applicant submits that the claims are enabled. Support for this amendment is found throughout the specification and at least on page 1, paragraph 5. No new matter has been added.

Accordingly, withdrawal of the rejection of claims 24 and 27-30 under 35 U.S.C. §112, first paragraph is respectfully requested.

The Examiner rejected claims 24 and 27-30 under 35 U.S.C. §112, second paragraph for being indefinite allegedly due to the omission of an essential step.

Applicant respectfully disagrees, but without acquiescing to the Examiner's position and in the interest of furthering prosecution, has amended claim 24 to recite a method for diagnosing cancer in a patient comprising performing an additional assay to determine if a patient has cancer if the quantitative amount of genome equivalents in a stool sample is above a predetermined threshold amount. Support for this amendment is found throughout the specification and at least on page 1, paragraphs 5 and 6. No new matter has been added.

Accordingly, withdrawal of the rejection of claims 24 and 27-30 under 35 U.S.C. §112, second paragraph is respectfully requested.

Rejections Under 35 U.S.C. §103(a)

The Examiner rejected claims 1, 4-8, 11, 14, 17-21, 24 and 27-30 under 35 U.S.C. §103(a) as being unpatentable over Shuber *et al.* (US 6,268,136 B1) in view of Ahlquist *et al.* (Gastroenterology, 2000, 119:1219-1227) and Hromadnikova *et al.* (BMC Pregnancy and Childbirth, 5/28/02). The Examiner also rejected claims 1, 4-8, 11, 14, 17-21, 24 and 27-30 under 35 U.S.C. §103(a) as being unpatentable over Ahlquist *et al.* (Gastroenterology, 2000, 119:1219-1227) in view of Hromadnikova *et al.* (BMC Pregnancy and Childbirth, 5/28/02, 2(4):1:5).

Applicant respectfully disagrees. However, without acquiescing to the Examiner's position and in the interest of furthering prosecution, Applicant has amended the claims to recite that the quantitative amount of genome equivalents is measured by measuring an amount of fragments of less than 200 bp. Support for this amendment is found throughout the specification and at least on page 4, paragraph 33. The above-cited US patents and references do not teach measuring an

amount of fragments less than 200 bp to determine a quantitative amount of genome equivalents that is used to evaluate whether a patient is a candidate for additional testing for the presence of cancer.

Accordingly, withdrawal of this rejection is respectfully requested.

CONCLUSION

Applicant respectfully requests reconsideration. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

A check in the amount of \$1,810.00 is enclosed to cover the three month extension of time and RCE fees. If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825 under Docket No.: E0411.70037US00.

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Respectfully submitted,

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